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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/084,523	02/28/2002	Jeffrey Charles Trewella	JCT002	7718
7590	03/23/2004			
Jeffrey C. Trewella c/o Innovative Solution\$ Inc. 283 Hickory Drive Kennett Square, PA 19348				
			EXAMINER DAVIS, RUTH A	
			ART UNIT 1651	PAPER NUMBER

DATE MAILED: 03/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/084,523

Applicant(s)

TREWELLA, JEFFREY CHARLES

Examiner

Ruth A. Davis

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 December 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) 1-10 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's amendment and response has been received and entered into the case.

Claims 1 – 22 are pending; claims 1 – 10 are withdrawn from consideration; claims 11 – 22 have been considered on the merits. All arguments have been fully considered.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 11 – 20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter which was not described in the specification as originally filed, in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention. Specifically, the phrase “each portion containing stem cells” is not described in the specification. The specification as originally filed describes dividing material to be stored into at least two portions, however the specification does not describe dividing the material such that each portion must contain stem cells. Even though the method recites defraying costs of storage service for umbilical cord blood stem cells, the disclosure does not mention literally or by way of example, the divided material wherein each portion contains stem cells.

Rejections under 35 U.S.C. 112, second paragraph, have been withdrawn.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 11 – 14 and 21 – 22 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Gonzalez-Ryan in view of Annas.

Applicant claims a method for paying storage costs of cord blood, the method comprising dividing the blood into 2 portions both with stem cells, selling one portion and using the monies made to pay for the second portion. The method further includes recovering the blood from a donor followed by concentrating and stabilizing the blood before dividing the cord blood.

Gonzalez-Ryan discloses the costs of storing cord blood and options for paying storage costs (p.106). The blood is collected, stabilized (p.107) and concentrated (p.108).

Gonzalez-Ryan does not specifically teach the method of payment as claimed. However, Annas discloses companies selling cord blood for therapeutic use in the event a donor cannot pay the storage costs (p.1524). At the time of the claimed invention, one of ordinary skill in the art would have been motivated to pay for storing cord blood in any way available, since it was known to be costly. Moreover, one of ordinary skill in the art would have been motivated by

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Annas to sell cord blood in order to pay storage costs, as it was known to have monetary value as evidenced by Annas.

5. Claims 11 – 14 and 17 – 20 stand rejected under 35 U.S.C. 103(a) as being unpatentable over “Blood Plasma Pooling” in view of Annas.

Applicant claims a method for paying storage costs of cord blood, the method comprising dividing the blood into 2 portions each containing stem cells, selling one portion and using the monies made to pay for the second portion. The method further includes recovering the blood from a donor followed by concentrating, purifying and amplifying the blood before dividing the cord blood.

“Blood Plasma Pooling” teaches methods wherein blood is collected, purified, filtered, concentrated and pooled (amplifying) before dividing into aliquots for storage (p.1 – 5).

“Blood Plasma Pooling” does not teach the method of payment as claimed. However, Annas discloses companies selling cord blood for therapeutic use in the event a donor cannot pay the storage costs (p.1524). At the time of the claimed invention, one of ordinary skill in the art would have been motivated to pay for storing cord blood in any way available, since it was known to be costly. Moreover, one of ordinary skill in the art would have been motivated by Annas to sell cord blood in order to pay storage costs, as it was known to have monetary value as evidenced by Annas.

6. Claims 11 – 14, 17 – 18 and 21 – 22 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Kline and/or Wolf, Jr. in view of Annas.

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Applicant claims a method for paying storage costs of cord blood, the method comprising dividing the blood into 2 portions each containing stem cells, selling one portion and using the monies made to pay for the second portion. The method further includes recovering the blood from a donor followed by concentrating, purifying and stabilizing the blood before dividing the cord blood.

Kline teaches methods where cord blood is collected, stabilized, fractionated (purified) and concentrated (p.824). Kline discloses storing cord blood and the idea of selling the cord blood for profit when one can no longer pay for storage (p.827).

Wolf, Jr. teaches methods of processing and storing cord blood wherein the blood is collected, concentrated, purified and stabilized prior to dividing and storage (col.1 line 16-25, col.4 line 29-41).

The references do not teach the method of payment as claimed. However, Annas discloses companies selling cord blood for therapeutic use in the event a donor cannot pay the storage costs (p.1524). At the time of the claimed invention, one of ordinary skill in the art would have been motivated to pay for storing cord blood in any way available, since it was known to be costly. Moreover, one of ordinary skill in the art would have been motivated by Annas to sell cord blood in order to pay storage costs, as it was known to have monetary value as evidenced by Annas.

7. Claims 11 – 22 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Boyse in view of Annas.

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Applicant claims a method for paying storage costs of cord blood, the method comprising dividing the blood into 2 portions each containing stem cells, selling one portion and using the monies made to pay for the second portion. The method further includes recovering the blood from a donor followed by concentrating, diluting, purifying, amplifying and stabilizing the blood before dividing the cord blood.

Boyse teaches methods for storing cord blood, the method comprising collecting blood, stabilizing, concentrating, purifying (col.18), diluting and amplifying (col.18-19) fractions of the blood for cryogenic storage.

The references do not teach the method of payment as claimed. However, Annas discloses companies selling cord blood for therapeutic use in the event a donor cannot pay the storage costs (p.1524). At the time of the claimed invention, one of ordinary skill in the art would have been motivated to pay for storing cord blood in any way available, since it was known to be costly. Moreover, one of ordinary skill in the art would have been motivated by Annas to sell cord blood in order to pay storage costs, as it was known to have monetary value as evidenced by Annas.

Response to Arguments

Applicant argues that the references do not teach dividing the cord blood into portions, and selling portions of the blood to defray storage costs; that the examiner uses impermissible hindsight; and that the instant method has unexpected advantages such as solving the dilemma of paying for cord blood storage.

However, these arguments fail to persuade, because “Blood Plasma Pooling” specifically teaches dividing the blood into aliquots, Kline teaches fractioning (dividing) the blood, Wolf teaches dividing the blood prior to storage, and Boyse teaches fractionating the cells (or dividing the blood into at least 2 portions). Furthermore, while Annas does not specifically teach selling a portion to defray costs of storing a second portion, the reference certainly teaches selling cord blood for monetary gain. At the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to sell cord blood in the event that the storages costs can not be paid for its well known value, as disclosed by Annas. It would have been further obvious to one of ordinary skill in the art to maintain at least a portion of the blood, as storage of the cord blood is the purpose for needing the monetary gain. Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by Annas to sell a portion of cord blood with a reasonable expectation for successfully paying for storing another portion.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Regarding Applicant's argument that the method unexpectedly solves the problem of paying for cord blood storage, it is noted that Annas teaches selling cord blood for profit.

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Therefore the claimed method does not appear to have any unexpected advantage over the prior art.

Conclusion

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

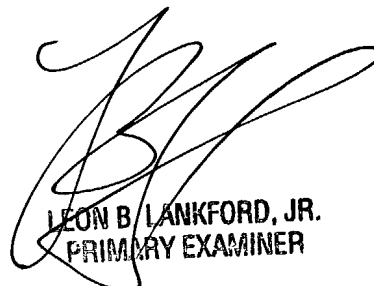
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruth A. Davis whose telephone number is 571-272-0915. The examiner can normally be reached on M-H (7:00-4:30); altn. F (7:00-3:30).

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ruth A. Davis; rad
March 16, 2004.



LEON B. LANKFORD, JR.
PRIMARY EXAMINER